UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,552	06/09/2005	Per Gisle Djupesland	44508-137	5912

21890 7590 01/09/2008

PROSKAUER ROSE LLP
PATENT DEPARTMENT
1585 BROADWAY
NEW YORK, NY 10036-8299

EXAMINER	
OSTRUP, CLINTON T	

ART UNIT	PAPER NUMBER
3771	

MAIL DATE	DELIVERY MODE
01/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,552	DJUPESLAND, PER GISLE	
	Examiner	Art Unit	
	Clinton Ostrup	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 May 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-43 are pending in this application.

Priority

The examiner acknowledges this application was filed as a United States National Phase Application of International Application Serial No. PCT/IB03/01557 filed March 28, 2003, which claims priority from United Kingdom application No. 0207422.7, filed March 28, 2002.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, "the mouthpiece which includes a flexible member which is deflectable on exhalation" claimed in claims 38-43 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28 and 35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 6,715,485. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are all drawn to nasal delivery devices for delivering a

substance to a nasal airway comprising a nasal delivery unit, a mouthpiece and a gas supply.

Claim 28 is drawn to a "nasal delivery device for delivering substance to a nasal airway of a subject, comprising: a mouthpiece through which a subject in use exhales; at least one delivery unit for delivering substance to a nasal airway of the subject on exhalation by the subject; and a gas supply unit for cycling a pressure in the nasal airway of the subject on exhalation by the subject."

Instant claim 28 can't be rejected by patented claim 1 because the patented claim 1 lacks a gas supply unit and a mouthpiece. Since patented claim 6 has all the limitations recited in the instant claim 28, and it is a broader version of the patented claim 6, claim 28 can be rejected by the patented claim 6.

Claim 35 is drawn to a "nasal delivery device for delivering substance to a nasal airway of a subject, comprising: a mouthpiece through which a subject in use exhales; at least one delivery unit for delivering substance to a nasal airway of the subject; and a gas supply unit for alternately delivering and withdrawing a volume of gas through the nasal airway of the subject such as to cause entrained substance to be flushed in alternate directions therethrough.

Claim 6 of 6,715,485 comprises a nasal delivery device comprising a delivery unit, a mouthpiece, and a gas supply unit; therefore, all the limitations of instant claims 28 and 35 are previously claimed in claim 6 of 6,715,485.

Claim 38-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 86-87 and 89 of

copending Application No. 10/520,380 and further in view of Keldmann et al., WO 1998/53869 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are all drawn to an interface member/unit comprising at least one nosepiece, a mouthpiece, and a flexible member/actuating unit.

Claim 38 is drawn to an "interface member for attachment to a nasal delivery device, comprising, as an integral element, at least one nosepiece for fitting to a nostril of a subject and a mouthpiece through which the subject in use exhales, wherein the mouthpiece includes a flexible member which is deflectable on exhalation into the mouthpiece. Claim 39 modifies the interface member to having first and second nosepieces for fitting to respective nostrils of a subject. Claim 40 modifies the interface member to be a disposable element. Claim 41 modifies the interface member to have a mouthpiece which comprises a tubular section through which the subject in use exhales.

10/520,380 claims a nasal delivery device for delivering substance to a nasal airway of a subject, comprising: a disposable interface unit, comprising at least one nosepiece unit for fitting to a respective nostril of a subject, a nozzle from which substance is in use delivered, a mouthpiece into which the subject in use exhales, and at least one delivery unit comprising a substance supply unit for delivering substance to the nozzle of the at least one nosepiece unit; and an actuation unit for actuating the at least one deliver,/unit of the interface unit.

Claim 87 of 10/520,380 adds the limitation wherein the interface unit is a single integral unit. Claim 89 of 10/520,380 is drawn to a nasal delivery device for delivering a substance to a nasal airway of a subject, comprising: a disposable interface unit, comprising (i) first and second nosepiece units for fitting to respective nostrils of a subject, each nosepiece unit comprising a nozzle from which substance is in use delivered, and (ii) first and second delivery units, each delivery unit comprising a substance supply unit for delivering~ substance to the nozzle of the respective nosepiece unit; and an actuation unit for actuating the delivery units of the interface unit.

Claims 38-41 differ from those in 10/520,380 in that the instant claims have a flexible member which is deflectable upon exhalation whereas claims 86, 87, and 89 have an actuation unit. Keldmann et al., WO 1998/53869 A1 teach a nasal delivery device wherein a slit is cut into a tube and that slit acts as an actuator unit (an actuator is a mechanical device for moving or controlling a mechanism or system) holding the substance in place until gas/air is supplied from the users mouth forcefully, at which point the actuator/flexible membrane moves and allows the substance to be dispersed in the nostril of the user. See: page 13, line 25- page 14, line 9 and figures 13 and 14. Therefore, it is clear that a flexible membrane can also act as an actuator.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Alving et al., (6,019,100).

Alving et al., teach a nasal delivery device (Figures 1A & 2) and a method for delivering a substance (Nitric Oxide (NO)) to a nasal airway of a subject, comprising: first and second nosepiece units (2), each including a nosepiece for fitting to respective nostrils of a subject (end of the catheters (2)); at least one substance supply unit (4 & 8) for supplying a substance for delivery to the nasal airway of the subject; and a valve unit (3A & 3B) for selectively fluidly connecting the at least one substance supply unit (4 & 8) alternately to respective ones of the nosepiece units (2), thus meeting the claim limitations of claims 1 and 16. See: abstract, col. 5, lines 5-47 and Figures 1A and 2.

Alving et al., teach a mouthpiece (9) being connected to the device (Figure 2) and that the exhaled air is re-circulated to the nasal passages and then back to the patient. Alving et al., teach a pump (3A) as providing air comprising NO into one nasal passage of the patient and another pump (3B) for facilitating in the removal of air from the nasal passage and that the pumps (3A & 3B) can be adjusted using the control unit (7) and the ventilator to suit conditions. Therefore, Alving et al., teach the specific limitations of claims 2-6, 17-20, 26 and 28-34. The reference teaches one nasal inlet

and one nasal outlet as shown in (Figure 2) or simultaneous aspiration and replenishment of both nostrils and that by using a thee-way valve the aspiration/pumping can be alternated between nostrils. Thus, Alving et al., teach the limitations of claims 12-15, 26, and 35. See: col. 5, line 5 – col. 6, line 22.

Claims 7-11 and 35 have intended use limitations; however, these claims are to a device. The intended use limitations do not add **structural** limitations to device clams. Regardless, it appears the device taught by Alving et al., would inherently be capable of performing the intended uses as claimed because Alving et al., describe the same method steps of using the device as claimed in claims 7-11 and 35. See: col. 5, line 26 col. 6, line 22.

Claims 28-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Djupesland et al., (WO 00/51672).

Djupesland et al., teach a delivery device and a method of delivering a substance to the nasal airway of a subject comprising a mouthpiece (26) through which a subject in use exhales; at least one delivery unit (22) for delivering substance to a nasal airway of the subject on exhalation by the subject; and a gas supply unit (32) for cycling a pressure in the nasal airway of the subject on exhalation by the subject. The Djupesland et al., reference teaches the air flows from the exhalation of air from the subject and that the subject can deliver differing levels of air flow which can then be adjusted and maintained by a resister (28). Therefore, Djupesland teach a device meeting the claim limitations of claims 28-35. See: page 7, lines 4 – page 10, line 10; page 17, line 15 – page 19, line 13 and Figures 2 & 3.

Claims 38 and 40-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Keldmann et al., (WO 98/53869).

Keldmann et al., teach a device for applying a powder to the mucus membrane of a nostril. The Keldmann et al., reference teaches a disposable device (10) that is flexible, has a flexible member which is deflectable (24), the mouthpiece having a tubular section and that a cavity is defined by the flexible member (area between the nosepiece (12) and the flexible member). The reference teaches using a corrugated device which would inherently be resilient (relative to the other part of the device) at the folds. Therefore, Keldmann et al., clearly teach the device as claimed in claims 38 and 40-43. See: abstract, page 13, line 25 – page 14, line 5 and Figures 1-3, 6, 13, and 18-20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 38 and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Djupesland et al., (WO 00/51672) as applied to claims 28-35 above and further in view of suggestions in the specification.

Djupesland et al., describe a nasal delivery comprising at least one nosepiece for fitting to a nostril of a subject (30) and a mouthpiece (26) through which the subject in use exhales, wherein the mouthpiece includes a flexible member (28) which is

deflectable on exhalation into the mouthpiece; however, the Djupesland et al., reference does not specifically teach these as being an interface member with the nosepiece and mouthpiece as integral elements.

Djupesland et al., describe how the delivery device comprises an oral exhalation unit (20) and a substance delivery unit (22) as separate components, but alternatively could be detachably coupled, for example by means of Velcro TM fasteners, connected, for example by means of screws and/or rivets, or even integrally formed. See: page 17, line 15 – page 19, line 13.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the delivery device as shown by Djupesland et al., by using the fasteners as suggested by Djupesland et al., because of the reasonable expectation of obtaining a compact, easy to use, one-piece nasal delivery device.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alving et al., (6,019,100) as applied to claims 1-37 above and further in view of the Djupesland et al., (WO 00/51672).

Alving et al., teach a nasal delivery device (Figure 2) and a method for delivering a substance (Nitric Oxide (NO)) to a nasal airway of a subject, comprising: first and second nosepiece units (2), each including a nosepiece for fitting to respective nostrils of a subject (end of the catheters (2)); at least one substance supply unit (4 & 8) for supplying substance for delivery to the nasal airway of the subject; and a valve unit (3A & 3B) for selectively fluidly connecting the at least one substance supply unit (4 & 8) alternately to respective ones of the nosepiece units. However, the Alving et al.,

reference does not specifically teach these units as being an interface member with the nosepiece and mouthpiece as integral elements of said interface member. See: col. 5, line 5 – col. 6, line 22

Djupesland et al., describe how the delivery device comprises an oral exhalation unit (20) and a substance delivery unit (22) as separate components, but alternatively could be detachably coupled, for example by means of Velcro TM fasteners, connected, for example by means of screws and/or rivets, or even integrally formed. See: page 17, line 15 – page 19, line 13.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the delivery device of Alving et al., by attaching the nosepiece and mouthpiece units into a single member by using the fasteners as suggested by Djupesland et al., because of the reasonable expectation of obtaining a compact, easy to use, one-piece nasal delivery device capable of delivering a substance to both nostrils.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Derrick (5,046,491) and Djupesland (WO 2002/068029 A2).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (571) 272-5559. The examiner can normally be reached on M-F 7:30-5 pm with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Clinton Ostrup
Examiner
Art Unit 3771

JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

1/7/08